May 4, 2022

Foshan Nanhai Plus Medical CO LTD
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street, Panyu
District
Guangzhou, Guangdong 510006
China

Re: K211036
Trade/Device Name: Plus Medical Chemotherapy Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA, QSO
Dated: April 1, 2022
Received: April 7, 2022

Dear Olivia Meng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bifeng Qian, M.D., Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211036

Device Name
Plus Medical Chemotherapy Gown

Indications for Use *(Describe)*
Plus Medical Chemotherapy Gowns are intended to protect healthcare personnel from exposure to chemotherapy drugs during preparation, handling and administration. The gowns are a closed back design, single use, disposable medical device provided sterile and non-sterile. Non-sterile gowns are to be sold in bulk to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and Sterile surgical gowns are to be sold directly to users after EtO sterilization validation to ISO 11135-1.

Plus Medical Chemotherapy Gown meets the barrier protection requirements of AAMI Level 4 per ANSI/AAMI PB70:2012. Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

Plus Medical Chemotherapy Gown has been evaluated for resistance to permeation of various chemotherapy drugs per ASTM F739-12 Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact. Testing data is provided per test procedure ASTM F739-12, the following 12 chemotherapy drugs has no breakthrough at the Standardized Breakthrough Rate of 0.1ug/cm2/minute, up to 480 minutes.

Test Chemotherapy Drugs Average Standardized Breakthrough Time
Carmustine (BCNU) [3.3mg/ml] >480mins
Cisplatin [1.0mg/ml] >480mins
Cyclophosphamide (Cytoxan) [20.0mg/ml] >480mins
Dacarbazine [10.0mg/ml] >480mins
Doxorubicin HCI [2.0mg/ml] >480mins
Etoposide [20.0mg/ml] >480mins
Fluorouracil [50mg/ml] >480mins
Methotrexate [25mg/ml] >480mins
Mitomycin C [0.5mg/ml] >480mins
Paclitaxel [6.0mg/ml] >480mins
Thio Tepa [10mg/ml] >480mins
Vincristine Sulfate [1.0mg/ml] >480mins
*No permeation was detected at either the minimum detectable permeation or 0.1ug/cm2/minute.
When chemotherapy drugs are present, gown selection should be based on the specific type(s) of chemicals used. Users are recommended to review drug labeling or material safety data sheets for the chemicals being used to determine an adequate level of protection.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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